**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-472/S-007

Banner Pharmacaps Inc.
Attention: Dale Kruep, Ph.D.
Director, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Dr. Kruep:

Please refer to your supplemental new drug application dated October 26, 2006, received October 27, 2006, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 200 mg ibuprofen capsules.

This supplemental new drug application provides for the addition of the warning statement "Ask a doctor or pharmacist before use if you are [bulleted] taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin." to the Drug Facts label for the 40- and 200-count package sizes in response to the September 26, 2006 supplemental labeling request letter.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (40-count carton and 200-count immediate container labels submitted October 26, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplements NDA 21-472/S-007**" Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

*{See appended electronic signature page}*

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Joel Schiffenbauer

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